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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Mills, T. M. et al.  
Application No. : 10/040,010  
Filing Date : January 4, 2002  
Title : TREATMENT OF ERECTILE DYSFUNCTION  
Examiner : Unassigned  
Group Art Unit : 1614

Assistant Commissioner for Patents  
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Prior to examination on the merits, Applicants respectfully request that the above-identified U.S. non-provisional application be amended as follows:

IN THE SPECIFICATION:

Please delete the paragraph beginning on page 2, line 20, and replace it with the following paragraph:

a!

Previous work in the area of erectile dysfunction has focused on processes that result in smooth muscle relaxation. One mechanism which causes erection of the penis involves release of nitric oxide (NO), enabling relaxation of blood vessels in the cavernosal circulation during sexual stimulation. For example, the compound sildenafil (Viagra) is a type 5 phosphodiesterase inhibitor that potentiates the effects of local release of NO, thereby resulting in vascular smooth muscle relaxation. Studies have found sildenafil to have an overall 60% efficacy rate in the promotion of NO-mediated cavernosal vasorelaxation (Virag, R., *Urology* 54, 1073-77, 1999). Still, in those patients with severe erectile dysfunction (such as that resulting from diabetes or prostate surgery), sildenafil treatment was associated with a modest satisfaction rate (Jarow, I.P. *et al.*, *J. Urology*, 162, 722-725, 1999). Moreover, only 30% of patents studied chose sildenafil treatment alone (Virag, R., 1999).